

Remarks/Arguments:

In response to the Office Action, the applicants offer the following remarks. The remarks are provided in the order of the paragraphs as presented in the Office Action.

Claims 5, 7-10, and 12-48 are pending in the application. Claim 34 is canceled herewith.

Objection to the Specification

The Specification is amended herewith to remove the hyperlink at paragraph 0042, as required in the Office Action.

Joint Inventors

The Examiner notes that he presumes that the subject matter of the various claims of this application was commonly owned at the time the inventions covered therein were made, and reminds the applicants of the obligation under 37 CFR 1.56 to point out the inventor and invention date of each claim that was not commonly owned at the time a later invention was made, in order for the Examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f), or (g) prior art under 35 U.S.C. § 103(a). The applicants state that the subject matter of all of pending claims 5, 7-10, and 12-48 was commonly owned at the time the inventions claimed therein were made.

Rejections Under 35 U.S.C. § 103

Claims 5, 7-10, and 12-36 are rejected under 35 U.S.C. § 103(a) as unpatentable over United States Patent No. 5,498,709 issued to Navia et al. The applicants note that the Office Action states that claims 12-32 are rejected, but addresses arguments to claims 12-36. The applicants presume that the rejection is intended to apply to claims 12-36, and request notification if that understanding is incorrect.

Navia's disclosure in column 10 at lines 15-25 amounts to a very standard workup of an organic reaction, with a simple extraction of the product into a solvent followed by a washing of the product/solvent mixture with water. This befits the main subject matter of the patent, which is directed to a novel synthetic route. The workup and purification are nearly incidental to the invention, and are treated in commensurately little detail. Thus, there is little discussion of how to choose among the myriad possible purification methods that a person of ordinary skill

might consider. Rather, the skilled artisan reading Navia is led to do exactly what Navia does, and, as outlined in the next paragraph, this is significantly different from what is presently claimed. There is no suggestion that it might be a good idea to try any different sequence of steps, much less the particular sequences of the present invention.

Specifically, Navia consistently teaches transferring sucralose from a crude mixture including a first solvent (water) into a second solvent (such as ethyl acetate). The product is ultimately isolated by further workup of that mixture of sucralose in the second solvent, involving contacting that mixture with a third solvent (water) that is at least partially immiscible with the second solvent (ethyl acetate), but not at least partially immiscible with the first solvent (water). Nowhere does Navia teach or suggest the counterintuitive idea recited in the present claims, which involves washing the crude mixture containing a first solvent (e.g., water) with a second solvent (e.g., ethyl acetate) to transfer impurities, not sucralose, to the second solvent. Nor does Navia teach or suggest using a third solvent (e.g., ethyl acetate) that is at least partially immiscible with the first solvent to extract the sucralose into it, with sucralose being recovered from this third solvent.

Navia does not teach the element of claim 5 reciting extraction of a partially purified composition comprising sucralose, second impurities, and a first solvent with an at least partially immiscible solvent to transfer sucralose into that solvent while retaining the second impurities in the first solvent. Rather, he teaches directly extracting a crude (not partially purified) sucralose mixture containing both second and first impurities with such a solvent to transfer the sucralose into it. Therefore the cited reference does not provide all of the claim elements, and a *prima facie* case of obviousness has not been presented. Neither does Navia suggest performing two separate extractions (with second and third solvents, respectively) of the mixture containing sucralose, first and second impurities, and the first solvent as recited in (a) and (b) of claim 5. Rather, he extracts the mixture only once, and subsequently contacts that extract with another solvent. Nowhere does he suggest the idea of doing the stepwise removal of impurities from the crude sucralose, as is practiced in the present invention.

By using the inventive process, the inventors succeed in doing something that Navia did not (nor did he attempt to) do: they remove certain very difficult to deal with impurities ("first" impurities) that tend to resist being separated from sucralose during subsequent extraction and crystallization steps from the sucralose at an early step in the process, allowing the ultimate preparation of sucralose crystals with high purity and yield. If the second solvent is less polar than the first, the first impurities tend to be ones such as tetrachlorosucrose that are lower in polarity than sucralose. If the second solvent is more polar than the first, the first impurities

tend to be compounds such as mono- or dichlorosucrose that are higher in polarity than sucralose. All of the mono-, di-, and tetrachloro sucroses are difficult to separate from sucralose by crystallization, and thus a way has been found to remove at least portions of such materials prior to any further purification, if any. Nothing in Navia suggests this approach.

Claims 37-48 are rejected under 35 U.S.C. § 103(a) as unpatentable over Burke (AIC Book and Paper Group Annual, vol 3, 1984, 13-58) in combination with United States Patent No. 5,498,709 issued to Navia et al.

Claim 37 recites a process that is similar that that of claim 5, but it further specifies that the second solvent have a lower Hildebrand parameter than the first solvent. Thus the materials washed out of the crude sucralose tend to be those of lower polarity than sucralose. Impurities that are of higher polarity than sucralose are then removed by an additional washing of the now somewhat purified crude sucralose mixture with a solvent having a higher Hildebrand solubility parameter than that of the first solvent. Thus, both higher and lower polarity impurities are removed before any further purification of the sucralose, if any, is performed.

As noted above in regard to the rejection of claims 5, 7-10, and 12-36, Navia does not teach or suggest even the first step, i.e. the washing of the crude mixture to transfer first impurities into a second solvent. Nor of course does he teach or suggest a second washing step with a different solvent. The applicants further note that claim 37 requires the use of three different solvents (a first solvent, a second with lower polarity, and a third with higher polarity), and Navia never suggests anything of this sort.

Regarding claim 43, three solvents are again used, each with a different polarity. This again produces a sucralose solution (in the second solvent) wherein the amounts of both higher polarity and lower polarity impurities have been diminished before any further purification of the sucralose, if any, is performed. Again, Navia never teaches or suggests such a strategy for essentially cleaning the sucralose before final purification.

The crux of the Office Action arguments seems to be that the instantly claimed sequences of extractions with specified types of solvents amount to mere optimization of the recovery of suitably pure sucralose from the reaction mixture. The Office Action refers to some of the variables that might be manipulated in such an effort, including the order of the extraction steps, the solvents, and the ratios of the solvents. Indeed, this recitation underscores the essentially infinite number of variations that might be tried, considering the large number of solvents that could be chosen for each of the three solvents, even assuming

that one knew to use three, and not some other number of, solvents. The number of possibilities explodes when one considers whether to use crystallization as one (or more) of the purification steps, and if so, at what point and from what solvent. The present invention amounts to finding a needle in the very large haystack of possible permutations and combinations of extraction and crystallization steps outlined above, and Navia neither provides all of the elements in the claims, nor any suggestions directing the reader to the very specific limitations in the claims of the present invention. Thus, the applicants urge that the rejections under 35 U.S.C. § 103 are improper, and should be withdrawn.


Amendments

Claims 5, 7-9, 12, 37, and 43 are amended herewith to reduce potential ambiguity. Claim 33 has been amended to incorporate the limitations of claim 34, which is canceled herewith. No new matter has been added.

Conclusion

For all of the foregoing reasons, pending claims 5, 7-10, and 12-33, and 35-48 are in condition for allowance. The rejections under 35 U.S.C. § 103 should all be withdrawn, and favorable action is earnestly solicited.

Respectfully submitted,



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